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EXAMINER	
DORNBUSCH, DIANNE	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
08/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/724,021	ORR ET AL.	
	Examiner	Art Unit	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-21* is/are pending in the application.

4a) Of the above claim(s) *20-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed May 27, 2009 have been fully considered but they are not persuasive.

Applicant argues that Peterson fails to show a hollow body which they defined in the arguments as “having a space or cavity inside; not solid; empty" (www.dictionary.com). The examiner disagrees, as seen in Fig. 4, the elongated member (12) is hollow since it has the interior lumen which contains the sleeve (20) and the space where the second component (16) passes through as seen in Fig. 1.

Applicant further argues that the reason the elongated member (12) is not hollow is due to it containing the sleeve. The examiner disagrees since the elongated member and the sleeve are separate component where in the assembled configuration the sleeve is inside the hollow area of the elongated member (Fig. 4). It does not indicate that the elongated member (12) is not a hollow component, on the contrary it shows that it is hollow since it is capable of holding the sleeve inside it.

Note that even in the assembled configuration, the combination of the sleeve and elongated member is still hollow since the second component goes through the hollow area of the device.

In response to applicant's arguments, the recitation “a device for arthroscopically delivering a tissue scaffold to a damaged or injured tissue site” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a

process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In response to applicant's argument that Peterson does not teach that the first component is for receiving and dispensing the tissue scaffold, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In response to applicant's arguments with respect to the 103 rejection over Dragan in view of Peterson. Applicant argues that there is no reason to combine the two references and that a person of ordinary skill in the art would not look to combine the device of Dragan with a funnel-shape proximal end as disclosed by Peterson.

The examiner disagrees, since in the art of liquid management, a person of skill in the art would look to combine this two references since the funnel-shape in the proximal end would allow for an ease in fluid handling.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 6, 9-11, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson (6,447,489).

Peterson the following claimed limitations:

Claim 1: A device comprising: a first component (10) having a funnel-shaped proximal end (14) (Fig. 1 and Col. 3 Line 13), a distal end (Fig. 1), and an elongate, hollow body (12) extending therebetween (Fig. 1and 4), the elongate body defining a passageway (the passageway seen in Fig. 4, 11, and 12) extending from the flared proximal end to the distal end (Fig. 4 and 11); and a second component (16) having an elongate body with a tip at a distal end (18) (Fig. 1 and 11), the elongate body being configured to be removably disposed within the first component for sliding along the passageway (Fig. 1, 11, and 12).

Regarding the statement that the first component is for receiving and dispensing the tissue scaffold, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim 2: That the passageway includes a first, flared portion (the proximal end is flared as seen in Fig. 1 and 4) extending into a second, tubular portion (the second tubular portion is the passageway that is connected to the flared portion seen in Fig. 4).

Claims 3 and 11: That the first, flared portion has a curved tapered shape (Fig. 4). The flared portion is tapered to smoothly connect to the second tubular portion.

Claims 6 and 16: That the tip of the second component comprises a spherical tip (Fig. 11)

Claim 9: An instrument comprising: an insertion tube (10) having a funnel-shaped proximal end (14) (Fig. 1 and Col. 3 Line 13), a distal end (Fig. 1) and a hollow passageway extending therebetween (the passageway seen in Fig. 4, 11, and 12 where the portion 12 of the insertion tube is a hollow body as explained above); and an insertion rod (16) having an elongate shaft (Fig. 1, 11, and 12) extending into a handle (handle seen in Fig. 1) at a proximal end (Fig. 1) and a blunt tip (18 when closed as seen in Fig. 11) at a distal end (Fig. 11), the elongate shaft being configured to be removably disposed within the insertion tube for sliding along the passageway and contacting the tissue scaffold disposed within the insertion device (Fig. 1, 11, and 12). Regarding the use of a scaffold, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim 10: See rejection of claim 1 and 2.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 4, 7, 15, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson (6,447,489).

Claims 4 and 15:

Peterson teaches all the claimed limitations discussed above however, Peterson does not disclose that the flared proximal end of the first component has a diameter in the range of about 15 mm to about 50 mm.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Peterson with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Furthermore, the differences in concentration, temperature, size, or pressure will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration, temperature, size, or pressure is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05 (II).

Claims 7, 17, and 18:

Peterson teaches all the claimed limitations discussed above however, Peterson does not disclose that the spherical tip has a diameter in the range of about 6 mm to about 10 mm.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Peterson with the diameter range since it has been

held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Furthermore, the differences in concentration, temperature, size, or pressure will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration, temperature, size, or pressure is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05 (II).

6. Claims 5, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson (6,447,489) in view of Orth et al. (2002/0002360).

Peterson teaches all the claimed limitations discussed above however, Peterson does not disclose that the second, tubular portion has a diameter in the range of about 5 mm to about 17 mm.

Orth discloses that the second, tubular portion (the inner diameter of the cannula 30) has a diameter in the range of about 5 mm to about 17 mm ([0011]).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Peterson with the diameter range in view of the teachings of Orth in order to have a size similar to the size of the delivery unit or scaffolds that are used in the art.

Additionally, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Peterson with the diameter range since it has been held that discovering an optimum value of a result effective variable

involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

7. Claims 1-4, 6-11, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan et al. (6,328,715) in view of Peterson (6,447,489).

Claim 1:

Dragan discloses a device for arthroscopically delivering a tissue scaffold to a damaged or injured tissue site, comprising: a first component (28) for receiving and dispensing the tissue scaffold (Fig. 6) having a proximal end (30), a distal end (Fig. 5), and an elongate, hollow body (Fig. 6 where the body of 28 is seen) extending therebetween, the elongate body defining a passageway (the passageway seen in Fig. 6 where the component 12 and 26 are inserted into the body 28) extending from the flared proximal end to the distal end (Fig. 6); and a second component (26) having an elongate body with a tip at a distal end (34), the elongate body being configured to be removably disposed within the first component for sliding along the passageway (Fig. 6).

Regarding the statement that the first component is for receiving and dispensing the tissue scaffold, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Dragan teaches all the claimed limitations discussed above however, Dragan does not disclose that the proximal end of the first component is funnel-shaped.

Peterson discloses all the limitations discussed above including a first component (10) with a funnel-shaped proximal end (14) (Fig. 1 and Col. 3 Line 13).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Dragan with funnel-shaped proximal end in view of the teachings of Peterson in order to enable the second component to be easily introduced by the operator through the passageway of the first component.

Additionally, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to make the proximal end funnel-shaped since it is an obvious change in shape where the instrument will still have the same functionality In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (MPEP 2144.04).

Claim 2: Dragan discloses that the passageway includes a first, flared portion (the proximal end is flared as seen in Fig. 6A) extending into a second, tubular portion (the second tubular portion is the passageway that is connected to the flared portion seen in Fig. 6A).

Claims 3 and 11: Dragan discloses that the first, flared portion has a curved tapered shape (Fig. 6A). The flared portion is tapered to smoothly connect to the second tubular portion.

Claims 4 and 15:

Dragan teaches all the claimed limitations discussed above however, Dragan does not disclose that the flared proximal end of the first component has a diameter in the range of about 15 mm to about 50 mm.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Dragan with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Furthermore, the differences in concentration, temperature, size, or pressure will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration, temperature, size, or pressure is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05 (II).

Claim 6: Dragan discloses that the tip (34) of the second component (26) comprises a spherical tip (Fig. 5 and Col. 4 Lines 12-13).

Claims 7, 17, and 18:

Dragan teaches all the claimed limitations discussed above however, Dragan does not disclose that the spherical tip has a diameter in the range of about 6 mm to about 10 mm.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Dragan with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Furthermore, the differences in concentration, temperature, size, or pressure will not support the patentability of subject matter encompassed by the prior art unless there is

evidence indicating such concentration, temperature, size, or pressure is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05 (II).

Claim 8: Dragan discloses that the second component (26) further includes at least one sealing ring (48) around the elongate body proximal to the tip (34) as seen in Fig. 6.

Claim 9:

Dragan discloses an instrument for arthroscopically delivering a tissue scaffold to a damaged or injured tissue site, comprising: an insertion tube (28) having a proximal end, a distal end (Fig. 5 an 6) and a hollow passageway extending therebetween (the passageway seen in Fig. 6 where the component 12 and 26 are inserted into the body 28); and an insertion rod (26) having an elongate shaft (Fig. 5) extending into a handle (42) at a proximal end (Fig. 5) and a blunt tip (34) at a distal end (Fig. 5), the elongate shaft being configured to be removably disposed within the insertion tube for sliding along the passageway and contacting the tissue scaffold disposed within the insertion device (Fig. 6). The elongated shaft is in contact with the tissue scaffold since it is in immediate proximity or in association (Dictionary.com definition of contact: immediate proximity or association) with the tissue scaffold as seen in Fig. 6.

Regarding the use of a scaffold, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Dragan teaches all the claimed limitations discussed above however, Dragan does not disclose that the proximal end of the insertion tube is funnel-shaped.

Peterson discloses all the limitations discussed above including an insertion tool (10) with a funnel-shaped proximal end (14) (Fig. 1 and Col. 3 Line 13).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Dragan with funnel-shaped proximal end in view of the teachings of Peterson in order to enable the insertion rod to be easily introduced by the operator through the passageway of the insertion tube.

Additionally, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to make the proximal end funnel-shaped since it is an obvious change in shape where the instrument will still have the same functionality In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (MPEP 2144.04).

Claim 10: Dragan discloses that the passageway includes a first, flared portion (the proximal end is flared as seen in Fig. 6A) extending into a second, tubular portion (the second tubular portion is the passageway that is connected to the flared portion seen in Fig. 6A).

Claim 16: Dragan discloses that the blunt tip (34) of the insertion rod comprises (26) a spherical tip (Fig. 5 and Col. 4 Lines 12-13).

Claim 19:

Dragan teaches all the claimed limitations discussed above however, Dragan does not disclose that the insertion rod further includes a pair of sealing rings around the elongate body.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have a second sealing ring since the examiner is taking Official Notice that the use of a second sealing ring is well known in the art in order to control the sliding resistance between the first components and the second component as well as providing a seal.

8. Claims 5, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan et al. (6,328,715) in view of Peterson (6,447,489) and further in view of Orth et al. (2002/0002360).

Dragan in view of Peterson teaches all the claimed limitations discussed above however, Dragan in view of Peterson does not disclose that the second, tubular portion has a diameter in the range of about 5 mm to about 17 mm.

Orth discloses that the second, tubular portion (the inner diameter of the cannula 30) has a diameter in the range of about 5 mm to about 17 mm ([0011]).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Dragan in view of Peterson with the diameter range in view of the teachings of Orth in order to have a size similar to the size of the delivery unit or scaffolds that are used in the art.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/Darwin P. Erezo/
Primary Examiner, Art Unit 3773